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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

TSUYOSHI YAMAGATA, ET AL.

Application No.: 10/562,635

Filed: December 29, 2005

For: PHARMACEUTICAL  
COMPOSITION

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:  
Examiner: Not Yet Assigned  
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Group Art Unit: 1645  
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July 19, 2006

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SUBMISSION OF MISCELLANEOUS PCT FORMS

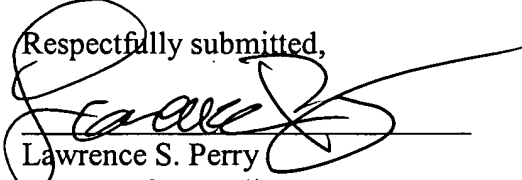
Sir:

Enclosed to complete the record and for the Examiner's convenience is Form PCT/IB/338, an English translation of the International Preliminary Report on Patentability (Form PCT/IB/373) and the Written Opinion of the International Searching Authority (Form PCT/ISA/237) in the above-identified application. The references discussed in the Written Opinion (or their patent family member equivalents) were all cited in Applicants' May 25, 2006 Information Disclosure Statement.

Entry hereof is earnestly solicited.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



Lawrence S. Perry  
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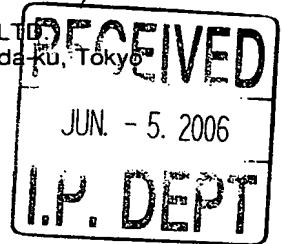
From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

To:

Y a - H n  
KYOWA HAKKO KOGYO CO., LTD.  
6-1, Ohtemachi 1-chome, Chiyoda-ku, Tokyo  
1008185  
JAPON



Date of mailing (day/month/year)  
26 May 2006 (26.05.2006)

Applicant's or agent's file reference  
1589

**IMPORTANT NOTIFICATION**

International application No.  
PCT/JP2004/010521

International filing date (day/month/year)  
16 July 2004 (16.07.2004)

Applicant

KYOWA HAKKO KOGYO CO., LTD. et al

**1. Transmittal of the translation to the applicant.**

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

**2. Transmittal of the copy of the translation to the designated or elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

**3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

Yoshiko Kuwahara

Facsimile No.+41 22 740 14 35

Facsimile No.+41 22 338 90 90

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

|  |  |  |
|--|--|--|
| Applicant's or agent's file reference<br>1589  | <b>FOR FURTHER ACTION</b>  | See item 4 below   |
| International application No.<br>PCT/JP2004/010521   | International filing date ( <i>day/month/year</i> )<br>16 July 2004 (16.07.2004) | Priority date ( <i>day/month/year</i> )<br>16 July 2003 (16.07.2003) |
| International Patent Classification (8th edition unless older edition indicated)<br>See relevant information in Form PCT/ISA/237 |  |  |
| Applicant<br>KYOWA HAKKO KOGYO CO., LTD.   |  |  |

|                                     |   |   |           |                     |                          |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
|-------------------------------------|---|---|-----------|---------------------|--------------------------|------------|----------|-------------------------------------|-------------|--|--------------------------|------------|----------------------------|-------------------------------------|-----------|---|--------------------------|------------|-------------------------|--------------------------|-------------|--|--------------------------|--------------|---|
| 1.                                  | This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).   |   |           |                     |                          |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| 2.                                  | This REPORT consists of a total of 5 sheets, including this cover sheet.<br><br>In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.   |   |           |                     |                          |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| 3.                                  | <p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 60%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> | <input checked="" type="checkbox"/>   | Box No. I | Basis of the report | <input type="checkbox"/> | Box No. II | Priority | <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | <input type="checkbox"/> | Box No. IV | Lack of unity of invention | <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | <input type="checkbox"/> | Box No. VI | Certain documents cited | <input type="checkbox"/> | Box No. VII | Certain defects in the international application | <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |
| <input checked="" type="checkbox"/> | Box No. I   | Basis of the report   |           |                     |                          |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>            | Box No. II  | Priority  |           |                     |                          |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input checked="" type="checkbox"/> | Box No. III   | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |           |                     |                          |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>            | Box No. IV  | Lack of unity of invention  |           |                     |                          |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input checked="" type="checkbox"/> | Box No. V   | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |           |                     |                          |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>            | Box No. VI  | Certain documents cited   |           |                     |                          |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>            | Box No. VII   | Certain defects in the international application  |           |                     |                          |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>            | Box No. VIII  | Certain observations on the international application   |           |                     |                          |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| 4.                                  | The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).  |   |           |                     |                          |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |

|   |   |
|---|---|
| The International Bureau of WIPO<br>34, chemin des Colombettes<br>1211 Geneva 20, Switzerland | Date of issuance of this report<br>15 May 2006 (15.05.2006)   |
| Facsimile No. +41 22 740 14 35  | Authorized officer<br><br><div style="text-align: center; font-weight: bold;">Yoshiko Kuwahara</div> Telephone No. +41 22 338 90 90 |

# PATENT COOPERATION TREATY

TRANSLATION

From the  
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing  
(day/month/year)

Applicant's or agent's file reference

**1589**

**FOR FURTHER ACTION**

See paragraph 2 below

|   |   |   |
|---|---|---|
| International application No.<br><b>PCT/JP2004/010521</b> | International filing date (day/month/year)<br><b>16.07.2004</b> | Priority date (day/month/year)<br><b>16.07.2003</b> |
|---|---|---|

International Patent Classification (IPC) or both national classification and IPC

Applicant

**KYOWA HAKKO KOGYO CO., LTD.**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

|  |                    |
|--|--------------------|
| Name and mailing address of the ISA/JP | Authorized officer |
| Facsimile No.                          | Telephone No.      |

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/010521

Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language  
\_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material  
☐ in written format  
☐ in computer readable form
  - c. time of filing/furnishing  
☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/010521

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 19-21

because:

☒ the said international application, or the said claims Nos. 19-21

relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claims 19-21 include a method for treatment of the human body by therapy, which does not require an examination by the International Preliminary Examining Authority.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 19-21

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/010521

Box No. V Reasoned statement under Rule 43bis 1(a)(i) with regard to novelty, inventive step or industrial applicability:  
citations and explanations supporting such statement

|                               |        |      |     |
|-------------------------------|--------|------|-----|
| 1. Statement                  |        |      |     |
| Novelty (N)                   | Claims | 1-18 | YES |
|                               | Claims |      | NO  |
| Inventive step (IS)           | Claims |      | YES |
|                               | Claims | 1-18 | NO  |
| Industrial applicability (IA) | Claims | 1-18 | YES |
|                               | Claims |      | NO  |

2. Citations and explanations:

Document 1: WO 02/078712 A1 (Kyowa Hakko Kogyo Co., Ltd.) 10 October 2002

Document 2: WO 02/62389 A1 (Ono Pharmaceutical Co., Ltd.) 15 August 2002

Document 1 cited in the ISR describes use of the compound described in formula (I) of the invention of this application for treatment of a hyperactive bladder symptom accompanying prostatic hypertrophy.

Thus, document 2 likewise describes combined use of an anticholinergic as a drug for treatment of prostatic hypertrophy.

This being the case, combining the subject matter of document 1 and document 2 and using the anticholinergic as the compound represented by formula (I) of the invention of this application is found to be easily conceived of by a person skilled in the art.